Remarks

Rejections under 35 U.S.C. 102

Claims 18-22, 24, 25, 28 and 33 were rejected under 35 U.S.C. 102(b) as disclosed by U.S. patent No. 5,716,404 to Vacanti, et al. ("the '404 patent"). Claims 18, 19, 21, 22, 24, 25, 28 and 33 were rejected under 35 U.S.C. 102(b) as disclosed by U.S. Patent No. 5,885,610 to Vacanti, et al. ("the '610 patent"). These rejections are respectfully traversed.

The claims are drawn to a biological matrix, method of manufacture and method of use. The matrix of claim 18 has been defined by its method of manufacture as defined by original claim 24 and the claim has been amended to recite "consisting essentially of" rather than "comprising" to more clearly define the claimed composition. The phrase "spore like cell" in claim 18 has been moved to claim 24 and claim 18 only recites claims. The elements of the claims include:

A method of generating a living biological matrix in vitro, the method consisting essentially of

(1) obtaining a cell sample;

(b) disrupting the cell sample to create a mixture containing cells and cellular debris;

(c) culturing the mixture, retaining the cellular debris, in culture medium for a time and under conditions sufficient to form a living biological matrix *in vitro*; and

(d) separating the biological matrix from the culturing medium.

The two Vacanti patents describe isolation of cells by trypsin or collagenase digestion of tissue, then cell culture onto and within a polymeric matrix.

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There is NO digestion of cells; NO cellular debris in the cell culture of Vacanti.

In Vacanti, the matrix is formed by a mesh of polymeric fibers.

As defined by the claims, the mixture includes cells and cell LYSATE debris. The cell lysate debris forms the matrix; there is no exogenously added polymeric matrix.

To moot any issue about a polymeric matric "could" be included in the mixture, the claims has been amended to recite "consisting essentially" of, which clearly and unequivocally precludes adding a polymeric matrix to the cell-cellular debris mixture.

Accordingly, there are at least two differences between what is defined by Vacanti and what is claimed:

Vacanti digests tissues to dissociate cells which are then cultured; the antithesis of what is claimed where cells are lysed and mixed with cells in culture.

Vacanti adds a polymeric mesh matrix on which the cells attach and grow (See col. 3, line 49 to col. 9, line 12); in complete contrast to the present method where the cellular debris forms a matrix around the cells.

The '404 patent does not disclose a biological matrix comprising cells and cell debris. The '404 patent discloses cells within a polymeric matrix. Although the polymer may be a natural material such as fibrin, this is not cell debris or fragments.

There is no disclosure in the '404 patent of disrupting cells to produce cell debris. Cellular debris is formed by lysing cells -- killing the cells. In contrast, the '404 patent specifically teaches that one wants the cells to attach, proliferate and form functional tissue. There is no process that would result in cell death, much less retention of dead cellular material.

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The '610 patent is similar to the '404 patent in that it relates to tissue engineering. As described in the application, the matrices are seeded with cells. The "digestion" is to digest the tissue, not the cells, with collagenase, which degrades the extracellular matrix so that the tissue dissociates into the individual cells. Blood does not contain cellular debris.

Allowance of all claims 1-33 is earnestly solicited.

Respectfully submitted,

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